



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration ^{3/5/98} D1424 B

February 12, 1998

WARNING LETTER
CHI-14-98

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gerber Products
445 State Street
Fremont, MI 49412-1056

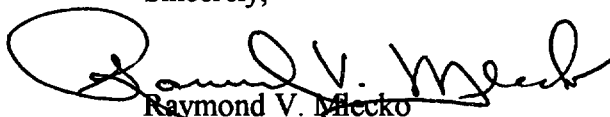
Dear Sir/Madam:

On October 14, 1997, we notified you of our intent to inspect a shipment of digital thermometers offered for import into the United States by your firm on October 13, 1997, under entry number [REDACTED]. This shipment was not held intact and was moved to the importer's premises and distributed without an FDA release. This is a violation of Title 21, Code of Federal Regulations, Section 1.90 (copy enclosed), which requires the importer to hold an entry intact pending receipt of a "May Proceed" or "Release" Notice from FDA.

Failure to prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to prevent future violations. Your written reply should be addressed to this office, attention Robert A. Sittig, Compliance Officer.

Sincerely,


Raymond V. Miccko
District Director

Enclosure